IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., *Plaintiff*, v. HETERO USA, INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LTD., and SUN PHARMACEUTICAL INDUSTRIES, LTD. *Defendants*.	C.A. No. 23-1332 (MN) (Consolidated)

DEFENDANTS AUROBINDO PHARMA USA, INC.'S AND AUROBINDO PHARMA LIMITED'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Aurobindo Pharma USA, Inc. ("Aurobindo Pharma USA") and Aurobindo Pharma Limited ("Aurobindo Pharma Ltd." and together with Aurobindo Pharma USA, "Aurobindo"), by and through their undersigned counsel, hereby submit the following Answer and Defenses ("Answer") and Counterclaims in response to the Complaint ("Complaint") filed by Plaintiff AbbVie Inc. ("Abbvie" or "Plaintiff").

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Aurobindo denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Aurobindo denies that Plaintiff is entitled to the relief requested or any other relief. Aurobindo responds to the Complaint as follows.

RESPONSE TO "Nature of the Action"

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action arises from Aurobindo's submission of Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of AbbVie's highly successful pharmaceutical product RINVOQ®, prior to the expiration of United States Patent No. RE47,221 ("the RE'221 Patent") (collectively, "the Patent-in-Suit").

ANSWER: Paragraph 1 alleges legal conclusions to which no response is required. To the extent a response is required, Aurobindo admits that Plaintiff's Complaint purports that this is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and under 35 U.S.C. § 271. Aurobindo denies any such infringement. Aurobindo admits that Plaintiff's Complaint purports that this is an action arising from Aurobindo's submission to the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of RINVOQ® prior to the expiration of United States Patent No. RE47,221 ("the RE'221 Patent"). Aurobindo denies all remaining allegations of Paragraph 1.

2. In November 2023, Plaintiff filed related action *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332 (MN) (D. Del.) against, inter alia, Hetero, Aurobindo, Sandoz, and Sun for patent infringement arising from their respective ANDA submissions. In August 2024, Plaintiff filed related action *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 24-0924 (MN) (D. Del.) against Hetero, Aurobindo, and Sun. In November 2024, Plaintiff filed related action *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 24-1254 (MN) (D. Del.) against, Hetero, Aurobindo, Sandoz, and Sun. These actions have all been consolidated for all purposes, including trial. *See* C.A. No. 23-1332 (MN) (D. Del.) (D.I. 114). Subsequently, Aurobindo sent AbbVie a new Notice Letter dated February 19, 2025 with new purported Paragraph IV certification to the RE'221 Patent. Plaintiff has timely filed suit within 45 days of receipt of Aurobindo's newest Notice Letter.

ANSWER: Aurobindo admits that Plaintiff filed *AbbVie Inc. v Hetero USA, Inc. et al.*, C.A. No. 23-1332 (MN) (D. Del.) against Hetero, Aurobindo, Sandoz, and Sun alleging patent infringement. Aurobindo admits that Plaintiff filed *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 24-0924 (MN) (D. Del.) against Hetero, Aurobindo, and Sun. Aurobindo admits that Plaintiff filed *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 24-1254 (MN) (D. Del.) against Hetero, Aurobindo, Sandoz, and Sun. Aurobindo admits that these actions have been consolidated in C.A.

No. 23-1332. Aurobindo admits that Aurobindo sent AbbVie a Notice Letter dated February 19, 2025 notifying AbbVie that it filed a Paragraph IV Certification to the RE'221 Patent. AbbVie filed suit on April 4, 2025, which is within 45 days of February 19. Aurobindo denies all allegations of patent infringement.

RESPONSE TO "RINVOQ"

3. RINVOQ® (upadacitinib) is a ground-breaking, once-daily oral Janus kinase (JAK) inhibitor that has gained widespread medical acceptance. In less than five years since its first FDA approval on August 16, 2019, RINVOQ® has been approved to treat patients with a number of different immune-mediated diseases, including rheumatoid arthritis, psoriatic arthritis and ulcerative colitis. It has been used to treat more than 160,000 patients in the United States alone.

ANSWER: Aurobindo admits that according to the RINVOQ® label revised as of 4/2024, RINVOQ® (upadacitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers, adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers, adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable, adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers, adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers, adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers, and adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Aurobindo further admits that according to the RINVOQ® label revised as of 4/2024, RINVOQ® is recommended in once daily dosages for rheumatoid arthritis, psoriatic arthritis, ankylosing

spondylitis, non-radiographic axial spondyloarthritis, atopic dermatitis, ulcerative colitis, and Crohn's Disease. Aurobindo is without sufficient knowledge or information to form a belief as to the remaining allegations of Paragraph 3 and therefore denies those allegations.

4. Janus kinases (JAKs), including JAK1, JAK2, JAK3 and Tyrosine kinase 2 (Tyk2), are intracellular enzymes that play a pivotal role in signaling pathways arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate signal transducers and activators of transcription (STATs) which modulate intracellular activity including gene expression. RINVOQ®'s active ingredient, upadacitinib, modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. Upadacitinib has surprising selectivity for JAK1.

ANSWER: Aurobindo admits that according to the RINVOQ® label revised as of 4/2024, Janus kinase (JAK) inhibitors are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Aurobindo further admits that according to the RINVOQ® label revised as of 4/2024, within the signaling pathway, JAKs phosphorylate and activate signal transducers and activators of transcription (STATs) which modulate intracellular activity including gene expression. Aurobindo further admits that according to the RINVOQ® label revised as of 4/2024, upadacitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. Aurobindo is without sufficient knowledge or information to form a belief as to the remaining allegations of Paragraph 4 and therefore denies those allegations.

5. AbbVie invested more than 3.5 billion dollars in the development of RINVOQ® and in its extensive clinical development program, which includes more than 45 completed or ongoing company-sponsored clinical trials and has resulted in approvals for an unexpected array of onerous diseases of the immune system. AbbVie continues to invest in the clinical development of RINVOQ®.

ANSWER: Aurobindo is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 5 and therefore denies those allegations.

6. AbbVie's development of RINVOQ® is part of its long legacy of research in immunology and its track record to making life better for people living with immune-mediated diseases.

ANSWER: Aurobindo is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 6 and therefore denies those allegations.

7. RINVOQ® is currently approved for treatment of:

a. adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor ("TNF") blockers;
b. adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers;
c. adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable;
d. adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers;
e. adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers;
f. adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers;
g. adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy;
h. Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

ANSWER: Aurobindo admits that according to the RINVOQ® label revised as of 4/2024, RINVOQ® (upadacitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers, adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers, adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable, adults with moderately to severely

active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers, adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers, adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers, adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy, and patients two years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. To the extent there are any remaining allegations in Paragraph 7, Aurobindo denies those allegations.

8. RINVOQ® represents an important advance for patients with these conditions. RINVOQ® was designated as a "Breakthrough Therapy" by FDA for treatment of adult patients with moderate to severe atopic dermatitis who are candidates for systemic therapy, based on FDA's determination that RINVOQ® may offer substantial treatment advantages over existing options for patients with serious or life-threatening diseases. RINVOQ® is the first and only JAK inhibitor that is approved for both non-radiographic axial spondyloarthritis (nr-axSpA) and active ankylosing spondylitis (AS). RINVOQ® was also the first oral therapy to receive FDA approval for moderate to severe Crohn's disease.

ANSWER: Aurobindo is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 8 and therefore denies those allegations.

9. As a result of the inventive work of the AbbVie scientists responsible for development and formulation, RINVOQ® is available in 15 mg, 30 mg, and 45 mg extended-release tablets, which allow for convenient once daily oral dosing.

ANSWER: Aurobindo admits that according to the RINVOQ® label revised as of 6/2023, RINVOQ® (upadacitinib) is available in 15 mg, 30 mg, and 45 mg extended-release tablets. Aurobindo further admits that according to the RINVOQ® label revised as of 6/2023, RINVOQ® is recommended in once daily dosages for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, atopic dermatitis, ulcerative colitis, and Crohn's Disease. Aurobindo denies the remaining allegations of Paragraph 9.

RESPONSE TO "The Parties"

10. Plaintiff AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. AbbVie's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. Aurobindo is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 10 and there for denies those allegations.

11. AbbVie is the assignee and owner of the Patent-in-Suit.

ANSWER: Aurobindo admits that, on information and belief, according to publicly available information, AbbVie is the assignee of the Asserted Patents. Aurobindo is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 11, and therefore denies them. Aurobindo holds Plaintiff to strict proof of standing.

12. AbbVie holds NDA No. 211675 for RINVOQ®.

ANSWER: Aurobindo admits that the electronic version of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") identifies "AbbVie Inc." as the purported applicant for NDA No. 211675.

13. Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.

ANSWER: Aurobindo admits the allegations of Paragraph 13.

14. Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

ANSWER: Aurobindo admits the allegations of Paragraph 14.

15. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

ANSWER: Paragraph 15 contains allegations which are vague as to the term "collaborate" and phrase "nearer than arm's length," therefore Aurobindo is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 15 and therefore denies those allegations.

16. Aurobindo caused ANDA No. 218866 to be submitted to FDA and seeks FDA approval of ANDA No. 218866.

ANSWER: Aurobindo admits the allegations of Paragraph 16.

17. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. acted collaboratively in the preparation of ANDA No. 218866 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218866 and seeking to market the Aurobindo ANDA Products.

ANSWER: Paragraph 17 contains allegations which are vague as to the term "collaboratively," therefore Aurobindo is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 17 and therefore denies those allegations.

18. On information and belief, Aurobindo intends to commercially manufacture, market, offer for sale, and sell the Aurobindo ANDA Products throughout the United States, including in the State of Delaware, in the event FDA approves ANDA No. 218866.

ANSWER: Paragraph 18 contains allegations related to future conduct about which no final decisions have been made, and so Aurobindo denies those allegations. Aurobindo denies the remaining allegations of Paragraph 18.

19. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Aurobindo's ANDA Products, in the event FDA approves ANDA No. 218866.

ANSWER: Paragraph 19 contains allegations related to future conduct about which no final decisions have been made, and allegations which are vague as to the terms "collaboratively" and "material assistance," therefore Aurobindo is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 19 and therefore denies those allegations.

RESPONSE TO "Jurisdiction and Venue"

20. This is a civil action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271 and 28 U.S.C. §§ 1338(a), 2201, 2202.

ANSWER: Paragraph 20 alleges legal conclusions to which no response is required. To the extent a response is required, Aurobindo admits that Plaintiff's Complaint purports to be an action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271 and 28 U.S.C. §§ 1338(a), 2201, 2202. Aurobindo denies any such infringement. Aurobindo denies that Plaintiff is entitled to any relief and denies all remaining allegations of Paragraph 20.

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

ANSWER: Paragraph 21 alleges legal conclusions to which no response is required. To the extent a response is required, Aurobindo does not contest that this Court has subject matter jurisdiction for the purposes of this litigation only based on the facts alleged by Plaintiff.

22. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware. On information and belief, Aurobindo Pharma USA, Inc. is registered to do business as a domestic corporation in Delaware (File Number 3769913).

ANSWER: Paragraph 22 alleges legal conclusions to which no response is required. To the extent a response is required, Aurobindo admits that Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware and is registered to do business as a domestic corporation in Delaware under File Number 3769913. Aurobindo denies that this Court has personal jurisdiction over Aurobindo Pharma USA, Inc., whether by general or specific jurisdiction. Aurobindo does not contest that this Court has personal jurisdiction over Aurobindo for the purposes of this litigation only. Aurobindo denies the remaining allegations of paragraph 22.

23. Additionally, this Court has personal jurisdiction over Aurobindo Pharma Ltd. because, on information and belief, Aurobindo Pharma Ltd., inter alia, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Aurobindo's ANDA Products in the State of Delaware upon approval of ANDA No. 218866.

ANSWER: Paragraph 23 alleges legal conclusions to which no response is required. To the extent a response is required, Aurobindo denies that this Court has personal jurisdiction over it, whether by general or specific jurisdiction. Aurobindo does not contest that this Court has personal jurisdiction over Aurobindo for purposes of this litigation only. Aurobindo denies the remaining allegations of Paragraph 23.

24. On information and belief, Aurobindo is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Aurobindo manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

ANSWER: Aurobindo denies the allegations of Paragraph 24.

25. On information and belief, Aurobindo is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Aurobindo denies the allegations of Paragraph 25.

26. Aurobindo has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to AbbVie, which manufactures and markets RINVOQ® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by letters dated October 13, 2023; January 23, 2024; August 7, 2024; October 23, 2024; November 4, 2024; November 26, 2024; and February 19, 2025 sent by Aurobindo to AbbVie pursuant to 21 U.S.C. § 355(j)(2)(B), Aurobindo prepared and filed its ANDA with the intention of seeking to market Aurobindo's ANDA Products nationwide, including within this judicial district.

ANSWER: Aurobindo denies the allegations of Paragraph 26.

27. On information and belief, Aurobindo plans to sell the Aurobindo ANDA Products in the State of Delaware, list the Aurobindo ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Aurobindo ANDA Products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Paragraph 27 contains allegations related to future conduct about which no final decisions have been made, and so Aurobindo denies the allegations of Paragraph 27.

28. On information and belief, Aurobindo knows and intends that the Aurobindo ANDA Products will be distributed and sold in Delaware and will thereby displace sales of RINVOQ®, causing injury to AbbVie. Aurobindo intends to take advantage of its established channels of distribution in Delaware for the sale of the Aurobindo ANDA Products.

ANSWER: Aurobindo denies the allegations of Paragraph 28.

29. Aurobindo Pharma Ltd. regularly invokes the jurisdiction of the courts of this judicial district by pleading claims and counterclaims in pharmaceutical patent infringement actions in this judicial district. See, e.g., *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 23-1193-CFC, D.I. 10 (D. Del. Oct. 30, 2023); *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 22-1611-CFC, D.I. 9 (D. Del. Jan. 3, 2023); *Acadia Pharmaceuticals Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-985-RGA, D.I. 215 (D. Del. June 15, 2022). Aurobindo Pharma Ltd. has also not contested personal jurisdiction or venue in pharmaceutical patent litigation in this judicial district. See, e.g., *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 23-1193-CFC, D.I. 10 (D. Del. Oct. 30, 2023); *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 22-01611-CFC, D.I. 9 (D. Del. Jan. 3, 2023); *Acadia Pharmaceuticals Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-985-RGA, D.I. 215 (D. Del. June 15, 2022).

ANSWER: Paragraph 29 alleges legal conclusions to which no response is required. To

the extent a response is required, Aurobindo admits that Aurobindo Pharma Ltd. has previously been sued and asserted counterclaims in this judicial District. Aurobindo denies any remaining allegations of Paragraph 29.

30. In the alternative, this Court has personal jurisdiction over Aurobindo Pharma Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) AbbVie's claims arise under federal law; (b) Aurobindo Pharma Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aurobindo Pharma Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Aurobindo's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

ANSWER: Paragraph 30 alleges legal conclusions to which no response is required. To the extent that a response is required, Aurobindo denies that this Court has personal jurisdiction over it, whether by general or specific jurisdiction. Aurobindo does not contest that this Court has personal jurisdiction over Aurobindo for purposes of this litigation, only. Aurobindo denies the remaining allegations of Paragraph 30.

31. Venue is proper in this district for Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware.

ANSWER: Paragraph 31 alleges legal conclusions to which no response is required. To the extent that a response is required, Aurobindo Pharma USA, Inc. does not contest that venue is proper in this Court for purposes of this litigation only. Aurobindo denies the remaining allegations of Paragraph 31.

32. Venue is proper in this district for Aurobindo Pharma Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India and may be sued in any judicial district.

ANSWER: Paragraph 32 alleges legal conclusions to which no response is required. To the extent that a response is required, Aurobindo admits that Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, and Aurobindo Pharma Ltd. does not

contest that venue is proper in this Court for purposes of this litigation only. Aurobindo denies the remaining allegations of Paragraph 32.

33. Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. did not contest personal jurisdiction or venue in this judicial district in response to the complaints Plaintiff filed in *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 23-1332 (MN) (D. Del.) and *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 24-0924 (MN) (D. Del.) (consolidated). Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. asserted counterclaims invoking this Court's jurisdiction in their answers to both complaints.

ANSWER: Aurobindo admits the allegations of Paragraph 33.

RESPONSE TO "The Asserted Patent"

34. The RE'221 Patent, entitled "Tricyclic compounds," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on February 5, 2019. The RE'221 Patent is a reissue of U.S. Patent No. 8,426,411, which originally issued on April 23, 2013. A true and correct copy of the RE'221 Patent is attached hereto as Exhibit A. The RE'221 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

ANSWER: Paragraph 34 alleges legal conclusions to which no response is required. To the extent a response is required, Aurobindo admits that the patent attached as Exhibit A purports to be U.S. Patent No. RE47,221. Aurobindo admits that the patent attached is titled "Tricyclic Compounds" and that it states it was issued on February 5, 2019. Aurobindo admits that RE47,221 states that it is a reissue of U.S. Patent No. 8,426,411 which issued on April 23, 2013. Upon information and belief, and based upon Plaintiff's allegations, Aurobindo admits that RE47,221 is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with RINVOQ® 15 mg, 30 mg, and 45 mg tablets. To the extent Paragraph 34 contains any additional allegations, Aurobindo denies them.

RESPONSE TO ANDA No. 218866"

35. Aurobindo has submitted ANDA No. 218866 ("Aurobindo's ANDA") which seeks approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of purported generic versions of RINVOQ® 15 mg and 30 mg tablets ("Aurobindo's ANDA Products" or "the Aurobindo ANDA Products") prior to the expiration of the RE'221 Patent.

ANSWER: Aurobindo admits that it submitted Aurobindo's ANDA to obtain approval to engage in the commercial manufacture, use, or sale of an upadacitinib, extended release tablet, 15 mg and 30 mg, prior to the expiration of U.S. Patent No. RE47,221. Aurobindo denies the remaining allegations of Paragraph 35.

36. On information and belief, FDA tentatively approved Aurobindo's ANDA on January 3, 2025.

ANSWER: Aurobindo admits the allegations of Paragraph 36.

37. Aurobindo sent AbbVie a new Notice Letter dated February 19, 2025. Aurobindo's Notice Letter represented that Aurobindo had submitted new a purported Paragraph IV certification with respect to the RE'221 Patent, which is listed in the Orange Book for RINVOQ®.

ANSWER: Aurobindo admits that it sent AbbVie a Notice Letter dated February 19, 2025 notifying Plaintiff that Aurobindo had submitted to the United States Food and Drug Administration ANDA No. 218866 and that ANDA No. 218866 was submitted under 21 U.S.C. § 355(j)(1) and (2)(A) with a Paragraph IV certification with respect to U.S. Patent No. RE47,221. Aurobindo denies the remaining allegations of Paragraph 37.

38. According to applicable regulations, Notice Letters such as Aurobindo's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

ANSWER: Paragraph 38 contains a legal conclusion for which no response is required. To the extent a response is required, upon information and belief, Aurobindo admits the allegations of Paragraph 38.

39. For the claims of the RE'221 Patent, Aurobindo's Notice Letter failed to allege that its ANDA Products or the proposed administration of those Products would not meet the limitations of that claim.

ANSWER: Paragraph 39 alleges legal conclusions to which no response is required. To the extent a response is required, Aurobindo avers that the RE'221 Patent is invalid and Aurobindo's ANDA Product cannot meet limitations of invalid claims. Aurobindo denies any remaining allegations of Paragraph 39.

40. On information and belief, if FDA grants final approval of Aurobindo's ANDA, Aurobindo will manufacture, offer for sale, or sell its ANDA Products, within the United States, including within the State of Delaware, or will import its ANDA Products into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Products will directly infringe the RE'221 Patent, either literally or under the doctrine of equivalents, and Aurobindo will actively induce and/or contribute to the infringement of those patents.

ANSWER: Paragraph 40 contains legal conclusions to which no response is required. To the extent a response is required, Aurobindo denies the allegations of Paragraph 40 because they are contingent on the FDA's approval of Aurobindo's ANDA, which has not yet occurred and which is outside the control of Aurobindo. Accordingly, Aurobindo has not yet determined its future plan for the Aurobindo ANDA upadacitinib extended-release tablet, 15 mg and 30 mg product. Aurobindo denies infringement. Aurobindo denies the remaining allegations of Paragraph 40.

RESPONSE TO "Count 1"

41. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent a response is required, Aurobindo incorporates by reference its response to each preceding paragraph as if fully set forth herein.

42. On information and belief, Aurobindo has submitted or caused the submission of Aurobindo's ANDA to FDA, and thereby seeks FDA approval of Aurobindo's ANDA Products.

ANSWER: Aurobindo admits the allegations of Paragraph 42.

43. AbbVie owns all rights, title, and interest in and to the RE'221 Patent.

ANSWER: Aurobindo admits that, on information and belief, and according to publicly available information and the face of the patent, AbbVie is the assignee of U.S. Patent No. RE47,221. Aurobindo is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 43, and therefore denies them. Aurobindo holds Plaintiff to strict proof of standing.

44. Aurobindo's ANDA Products infringe one or more claims of the RE'221 Patent.

ANSWER: Aurobindo denies the allegations of Paragraph 44.

45. Aurobindo did not contest infringement of claims 13–14 of the RE'221 Patent in Aurobindo's February 19, 2025 Notice Letter. If Aurobindo had a factual or legal basis to contest infringement of the claims of the RE'221 Patent, it was required by applicable regulations to state such a basis in the Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

ANSWER: Aurobindo denies the allegations of Paragraph 45.

46. Aurobindo has infringed one or more claims of the RE'221 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the RE'221 Patent.

ANSWER: Aurobindo denies the allegations of Paragraph 46.

47. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the RE'221 Patent would infringe one or more claims of the RE'221 Patent under 35 U.S.C. § 271(a), and/or Aurobindo would induce the infringement of and/or contribute to the infringement of one or more claims of the RE'221 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Aurobindo denies the allegations of Paragraph 47.

48. Aurobindo had actual and constructive notice of the RE'221 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the RE'221 Patent would constitute an act of infringement of the RE'221 Patent.

ANSWER: Paragraph 48 alleges legal conclusions to which no response is required. To the extent a response is required, Aurobindo admits that U.S. Patent No. RE47,221 is listed in the

Orange Book in connection with Rinvoq®. Aurobindo denies the remaining allegations of Paragraph 48.

49. Aurobindo filed its ANDA without adequate justification for asserting that the RE'221 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the RE'221 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

ANSWER: Aurobindo denies the allegations of Paragraph 49.

50. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the RE'221 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Aurobindo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

ANSWER: Aurobindo denies the allegations of Paragraph 50.

RESPONSE TO "Request for Relief"

With respect to Plaintiff's request for relief, Aurobindo denies that Plaintiff is entitled to any relief for the allegations and claims made in the Complaint, including the relief requested in paragraphs A-H.

SEPARATE DEFENSES

Without prejudice to the denials set forth in this Answer, Aurobindo further responds to the Complaint with the defenses set forth below. Aurobindo expressly reserves the right to supplement this Answer, including the right to assert additional defenses as more information is learned through discovery and further factual investigation in this case. Aurobindo does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiff bears the burden of proof.

FIRST AFFIRMATIVE DEFENSE
(Non-infringement of the RE'221 Patent)

Aurobindo has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the RE'221 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of the RE'221 Patent)

The claims of the RE'221 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. § 282(b), or under other judicially-created bases for invalidation or unenforceability.

THIRD AFFIRMATIVE DEFENSE
(Equitable Defenses)

Any claim of relief by Plaintiff is barred, in whole or in part, by the equitable doctrines of unclean hands, estoppel, or patent misuse.

FOURTH AFFIRMATIVE DEFENSE
(Not An Exceptional Case)

Aurobindo's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

FIFTH AFFIRMATIVE DEFENSE
(No Willful Infringement)

Aurobindo has not willfully infringed, and will not willfully infringe, any claim of the RE'221 patent.

SIXTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Plaintiff is not entitled to any injunctive relief because, *inter alia*, any alleged injury to Plaintiff is not immediate or irreparable, Plaintiff has an adequate remedy at law, or public policy concerns weigh against any award of injunctive relief.

SEVENTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief may be granted.

EIGHTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

Reservation of Additional Defenses

Aurobindo reserves the right to assert additional separate defenses that may be developed through discovery, or otherwise, in this action, such as claims of inequitable conduct during the prosecution of the RE'221 patent.

AUROBINDO'S COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. (collectively, "Aurobindo"), by and through their counsel, brings the following Counterclaims against Plaintiff/Counter-Defendant AbbVie Inc. ("AbbVie" or "Counter-Defendant") for a declaratory judgment that U.S. Patent No. RE47,221 ("RE'221" or "the Asserted Patent") are invalid and/or not infringed by Aurobindo's upadacitinib extended-release tablet that is the subject of Abbreviated New Drug Application ("ANDA") No. 218866 ("Aurobindo's ANDA Product").

THE PARTIES

1. Counterclaim-Plaintiff Aurobindo Pharma Limited is a corporation organized and existing under the laws of the Republic of India with its principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

2. Counterclaim-Plaintiff Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520.

3. AbbVie Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

BACKGROUND

4. Aurobindo filed ANDA No. 218866 with the FDA seeking approval to market upadacitinib extended-release tablets, 15 mg and 30 mg, referencing the approved New Drug Application ("NDA") for RINVOQ®, NDA No. 211675.

5. The United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. RE47,221 ("RE'221") titled "Tricyclic Compounds", naming Plaintiff/Counterclaim-Defendant AbbVie Inc. as the assignee on the face of the patent, and listing an issue date of February 5, 2019. The patent states that it is a reissue of U.S. Patent No. 8,426,411, issued on April 23, 2013.

6. AbbVie is the current holder of NDA No. 211675.

7. The United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluation," also known as the "Orange Book," lists U.S. Patent No. RE'221 as covering RINVOQ® as manufactured under NDA No. 211675.

8. Aurobindo filed ANDA No. 218866 with the FDA seeking approval to market upadacitinib extended-release tablets, 15 mg and 30 mg, referencing the approved New Drug Application ("NDA") for RINVOQ®, NDA No. 211675.

9. As part of its ANDA, Aurobindo submitted to the FDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paragraph IV Certification") that RE'221 is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Aurobindo's ANDA.

10. On or about February 19, 2025, Aurobindo sent by FedEx and by email to Counterclaim-Defendant's counsel a letter concerning its Paragraph IV certification regarding RE'221 (the "February 2025 Notice Letter") to AbbVie Inc.

11. The February 2025 Notice Letter included a detailed statement of the factual and legal bases for Aurobindo's opinion that RE'221 is invalid, unenforceable, and/or not infringed by Aurobindo's Proposed ANDA Product.

12. Counterclaim-Defendant has actual knowledge of the contents of the February 2025 Notice Letter.

13. Aurobindo produced ANDA No. 218866 and DMF No. 38095 to Counterclaim-Defendant in *AbbVie Inc. v. Hetero USA, Inc. et al*., C.A. No. 23-1332 (MN) (D. Del.) in a case regarding other patents also listed in the Orange Book for Rinvoq®.

14. AbbVie filed the Complaint in this action on April 4, 2025.

15. On information and belief, Aurobindo's February 2025 Notice Letter was received by AbbVie on or about February 19, 2025.

16. WO 2009/152133 ("WO '133") was published on December 17, 2009, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

17. WO 2010/119284 ("WO '284") was published on October 21, 2010, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

18. WO 2010/119285 ("WO '285") was published on October 21, 2010, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

19. WO 2009/150240 ("WO '240") was published on December 17, 2009, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

20. WO 2009/047506 ("WO '506") was published on April 16, 2009, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

21. WO 2008/119792 ("WO '792") was published on October 9, 2008, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

22. WO 2008/078091 ("WO '091") was published on July 3, 2008, and is prior art to RE'221 under 35 U.S.C. § 102(a)(1).

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 1331, 1338(a), based on actual controversy between Aurobindo and Counter-Defendant arising under the patent laws of the United States, 35 U.S.C. §§ 100 et seq.

24. This Court has personal jurisdiction over Counterclaim-Defendant because Counterclaim-Defendant has voluntarily subjected itself to the Court's jurisdiction by filing the Complaint, and for other reasons.

25. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FIRST COUNTERCLAIM
(Declaration of Non-infringement of RE'221)

26. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-25 of the Counterclaims as if fully set forth herein.

27. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of RE'221 will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Proposed ANDA Product described by ANDA No. 218866.

28. The commercial manufacture, use, offer for sale, sale, or import of Aurobindo's Proposed ANDA Product has not infringed, does not infringe, and would not directly infringe or indirectly infringe any valid claim of RE'221, either literally or under the doctrine of equivalents, for at least the reasons Aurobindo presented in the February 2025 Notice Letter, which is incorporated herein by reference.

29. Further, Aurobindo will not infringe, contribute to the infringement of, or induce the infringement of any valid and/or enforceable claim of RE'221, and will not be liable for such infringement, for at least the reasons Aurobindo presented in the February 2025 Notice Letter, which is incorporated herein by reference.

30. By way of example and not limitation, Aurobindo will not infringe the claims of RE'221 because the Aurobindo ANDA Product will not meet all claim limitations.

31. Counterclaim-Defendant bears the burden of proving infringement and will not be able to meet that burden.

32. There is an actual and justiciable controversy between the parties concerning whether the manufacturing, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218866 will infringe any valid and enforceable claim of RE'221.

33. Aurobindo is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218866 will not infringe, directly or indirectly, any valid claim of RE'221.

SECOND COUNTERCLAIM
(Declaration of Invalidity of RE'221)

34. Aurobindo incorporates by reference the allegations set forth in Paragraphs 1-33 of the Counterclaims as if fully set forth herein.

35. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of RE'221 are invalid for failure to comply with the statutory prerequisites of 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases of invalidation and unenforceability.

36. In the February 2025 Notice Letter, Aurobindo explained reasons sufficient to show that the claims of RE'221 are invalid, yet Counterclaim-Defendant brought this case anyway.

37. All claims of RE'221 are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, the defenses recognized in 25 U.S.C. § 282(b), double patenting, and/or other judicially-created bases for invalidation, at least for the reasons stated in the February 2025 Notice Letter, which is incorporated herein by reference.

38. By way of example and not limitation, as described in the February 2025 Notice Letter, each claim of RE'221 is invalid under 35 U.S.C. § 103 in light of at least WO '133, WO '284, WO '285, WO '240, WO '506, WO '792, and/or WO '091.

39. There is no substantial difference between the claims of RE'221 and the disclosures of WO '133, WO '284, WO '240, WO '506, WO '792, and/or WO '091.

40. There are no secondary indicia of nonobviousness that have a nexus to the claims of RE'221.

41. By way of example and not limitation, as described in the February 2025 Notice Letter, each claim of RE'221 lacks utility under 35 U.S.C. § 101, and enablement and written description under 35 U.S.C. § 112.

42. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218866 will infringe any valid and enforceable claim of RE'221.

43. Aurobindo is entitled to a judicial declaration that the claims of RE'221 are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 or other judicially created bases for invalidation and unenforceability.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo respectfully requests the Court Enter a Judgment and Order in its favor and against Counterclaim-Defendants to include:

A. A declaration that the claims of RE'221 are invalid;

B. A declaration that Aurobindo's submission of ANDA No. 218866 seeking FDA approval to engage in the commercial manufacture, use, or sale of an upadacitinib extended-release tablet before the expiry of RE'221 has not infringed, and will not infringe, any valid claim of RE'221;

C. A declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, or importation of the upadacitinib extended-release tablet that is the subject of ANDA No. 218866 will not infringe, induce infringement, or contribute to any infringement of any valid claim of RE'221;

D. A declaration that Counterclaim-Defendant is entitled to no damages, interest, costs, or other relief from or against Aurobindo;

E. A declaration that this is an exceptional case under 35 U.S.C. § 285 and awarding Aurobindo's attorneys' fees, costs, and expenses;

F. A declaration that Counterclaim-Defendant is not entitled to any injunctive relief;

G. A declaration preliminarily and permanently enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from taking any action to unlawfully prevent the FDA approval of ANDA No. 218866 and the product described therein;

H. A declaration preliminarily and permanently enjoining Counterclaim-Defendant, its officer, agents, servants, employees, attorneys, and any person who acts in concert or participation with Counterclaim-Defendant, from asserting or otherwise seeking to enforce RE'221 against Aurobindo or anyone in privity with Aurobindo; and

I. Such other and further relief as the Court may deem proper.

Dated: June 16, 2025

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